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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,092	10/19/2001	S. Rao Cherukuri	24222-X2	6756

7590 07/15/2004

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	

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DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,092		
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-10 and 14-47* is/are pending in the application.

4a) Of the above claim(s) *14,15,19-28 and 31-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-10,16-18,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 04/23/04. In this amendment, applicants removed sodium alginate that was in original claim 2. In so doing, the prior art Krishnamurthy (US 5,508,043) cited in the last office action is no longer a prior art since Krishnamurthy does not disclose the erodible polymers now recited in generic claim 1.

Claims 1, 6-10 and 14-47 are pending. Applicants listed claim 18 as withdrawn from consideration. Claim 18 was examined and was not withdrawn because claim 18 is directed to fluoxetine antidepressant. Examiner respectfully requests applicants to make a note of this.

Response to Arguments

Applicants' argument, with respect to the cited prior art Krishnamurthy (US 5,508,043), is persuasive as it relates to the assertion that Krishnamurthy does not teach the erodible polymers now recited in generic claim 1. The argument is persuasive because the amendment to the generic claim removes Krishnamurthy as a prior art since Krishnamurthy does not disclose any of the erodible polymers of the amended claim 1. Thus, a new rejection follows in light of the amendment.

Regarding the issue that size of the caplet "aids in providing a controlled or extended release product with high levels of active ingredients and helps produce a product with uniform active ingredient content throughout." Applicants further state that "the size of the caplet also helps withstand mechanical pressure both in the processing of the caplet and the chewing of the product in the mouth so that the active ingredients are released in the stomach of the consumer. In addition, the smaller size of the product allowed for better controlled release of the active ingredients. The smaller size results in a different erosion pattern, yet the release of the active

ingredient is better controlled through the small size of the delivery medium. Thus the size of the caplet is an important feature of the present inventive subject matter."

1. The above arguments filed 04/23/04 have been fully considered but they are not persuasive.

Applicants have no comparable data to show that the caplet of Krishnamurthy in terms of the size does not meet all the arguments presented above or the size of the applicants caplet in relation to any known caplet does not have those attributes listed above. It would appear that it is the matrix or the extended or sustained or controlled release dosage forms that afford controlled release features to a dosage form. Applicants appear to argue that the smaller size of the caplet lends better controlled release of the active ingredients.

The rejection below addresses the amended claims. Claims 1, 6-10, 16-18, 29 and 30 are considered and claims 14, 15, 19-28 and 31-47 continue to be withdrawn from examination as non-elected claims.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 6-10, 16-18, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour (US 6,352,721).

Faour discloses the delivery of amitriptyline, fluoxetine, sertraline and venlafaxine tricyclic antidepressant agents (column 14, lines 55-60). Faour discloses that for oral, buccal and sublingual administration, the delivery device is formulated in the form of caplet or tablet

(column 17, lines 57 and 58). Hydroxyethylcellulose (column 9, line 13), carboxymethylcellulose sodium (column 10, line 50), magnesium or calcium stearate (column 10, lines 41 and 42), oils, fatty acid glycerides, emulsifying agents, flavor agents, coloring agents and disintegrants (column 11, line 49 to column 12 line 39) are included in the composition. Aspirin and cisapride are also deliverable by the delivery device of Faour (column 5, lines 59 and 60). Faour exemplifies the formulation with cisapride in example 1, and in that example silicon dioxide and magnesium stearate are included in the formation of the granules. Claim 29 recites migraine therapeutic that is further limited to amitriptyline, aspirin and varapamil and others by claim 30.

The difference between Faour and the instant claims is that the prior art Faour is silent in the length and diameter of the caplet. To the extent that applicants' argument may be directed to Faour, the response to the argument presented above is also applicable here. Caplets by their nature and design have dimensions of length and diameter and it is within the purview of the person of skill or ordinary skill in the art to have the capacity to measure the parameters of length and diameter. Although, applicants in the above argument state that the diameter and length of the caplet: a) "aid in providing a controlled or extended release product with high levels of active ingredients and helps produce a product with uniform active ingredient content throughout," b) "the size of the caplet also helps withstand mechanical pressure both in the processing of the caplet and the chewing of the product in the mouth so that the active ingredients are released in the stomach of the consumer," c) "the smaller size of the product allowed for better controlled release of the active ingredients," d) "the smaller size results in a different erosion pattern, yet the release of the active ingredient is better controlled through the

small size of the delivery medium," it is noted that there is no comparable data to demonstrate the above assertions. In the absence of a showing, the recited length and diameter of the caplet does not patentably distinguish the claimed caplet over the caplet of the prior art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the caplet formulation of Faour where the formulation comprises antidepressant, erodible polymer and lubricants. One having ordinary skill in the art would have been motivated to prepare the caplet of Faour with the expectation of orally delivering the antidepressants.

Observations Made:

Examiner would like to bring to applicants attention that claim 19 though withdrawn depends on cancelled claim 12. Also, silicon dioxide is listed as a lubricant. Is silicon dioxide used as a lubricant in this application? "Tripionate" in claim 1 appears to be a typographical error of ---tripropionate---

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
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